**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA, et al., ex rel. JULIANNE NUNNELLY and MATTHEW SHANKS, Plaintiffs, | ) | |
| v. | ) | Civil Action No. 20-cv-11401-PBS |
| REGENERON PHARMACEUTICALS, INC., Defendant. | ) | |

**MEMORANDUM AND ORDER**

April 29, 2025

Saris, D.J.

**INTRODUCTION**

In this qui tam action, the United States alleges that Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") fraudulently reported the average sales price ("ASP") of Eylea, a prescription drug used to treat age-related vision impairment, in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A) & (B), and was unjustly enriched. Similarly, the intervening States[1] bring claims under state analogs to the FCA.

[1] The complaint was initially brought by former Regeneron employees on behalf of the United States and certain States and localities. The United States ultimately intervened in this case against Regeneron (Dkt. 44). The States of Colorado, Georgia, Michigan, North Carolina, Texas, and Washington intervened shortly thereafter (Dkt. 55).

At its core, this case is about (1) whether Regeneron's practice of reimbursing third-party distributors for credit card processing fees constitutes a price concession provided to medical providers (like ophthalmologists) who purchase the drugs, which must be deducted from the ASP reported to the Centers for Medicare and Medicaid Services ("CMS") and (2) whether the fees constitute bona fide service fees which need not be deducted from ASP.

Regeneron moves to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). After a hearing, the Court **DENIES** Regeneron's motion to dismiss (Dkt. 145).

## BACKGROUND

### I. Factual Background

The following facts are taken from the complaints of the United States (Dkt. 58) and the intervening States (Dkt. 128). The Court accepts the facts as true at this stage. See Artuso v. Vertex Pharms., Inc., 637 F.3d 1, 5 (1st Cir. 2011).

#### A. Eylea

Regeneron is a pharmaceutical company that manufactures Eylea. Eylea is a physician-administered drug used to treat Neovascular Age-Related Macular Degeneration, commonly called Wet AMD, a prevalent disease among the elderly that gradually leads to vision impairment. After prescribing Eylea to patients, ophthalmologists inject the drug into the patients' eyes at medical offices on an outpatient basis.

To obtain Eylea, medical practices purchased the drug up front from third-party specialty distributors rather than directly from Regeneron. Under this arrangement, distributors first purchased Eylea wholesale from Regeneron and then sold it to medical providers. After an ophthalmologist prescribed and administered the drug to a patient, the ophthalmologist then submitted a reimbursement claim to Medicare or another payor. This practice is known as "buy and bill" under Medicare Part B.

**B. Medicare Part B Reimbursements**

Medicare Part B reimburses physicians for administered "buy and bill" drugs like Eylea based on the ASP of the drug, minus any patient co-pay. Regeneron is required by CMS to report the ASP of their manufactured drugs every quarter. The difference between the amount Medicare reimburses a physician for a drug and the amount the physician paid to purchase the drug is referred to as the "spread" and represents the physician's profit from the drug. The plaintiff-States also reimburse "buy and bill" drugs based on the ASP reported to CMS. Between 2012 and 2023, Medicare Part B spent more than $25 billion on Eylea reimbursements. The plaintiff-States estimate that between 2013 and 2024, they collectively spent more than $175 million on Eylea reimbursements.

**C. Calculating the ASP**

The ASP was first introduced as the method for calculating Medicare Part B reimbursements by the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, in part to address concerns that the previous pricing methodology -- which did not require manufacturers to deduct discounts -- inflated the costs of pharmaceutical drugs. Generally speaking, a drug's ASP represents the manufacturer's total sales divided by the total number of units of the drug sold in a quarter. 42 U.S.C. § 1395w-3a(c)(1)(A)-(B)). This statute requires that the ASP "include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under [the Medicaid program])." Id. § 1395w-3a(c)(3). The statute further states that "[f]or years after 2004, the Secretary may include in such price other price concessions . . . that would result in a reduction of the cost to the purchaser." Id. (emphasis added).

In 2006, CMS implemented the current regulations, which state in relevant part:

> (2) Price concessions.
>
> > (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:
> >
> > > (A) Volume discounts.
> > > (B) Prompt pay discounts.
> > > (C) Cash discounts.
> > > (D) Free goods that are contingent on any purchase requirement.

> (E) Chargebacks and rebates (other than rebates under the Medicaid program).
>
> (ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

42 C.F.R. § 414.804(a)(2) (emphasis added).

The regulations define "bona fide service fees" as:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Id. § 414.802.

**D. Regeneron's Use of Distributors**

Instead of selling directly to medical practices, Regeneron relied on third-party distributors to sell Eylea. Distributors such as Besse Medical ("Besse"), McKesson Corporation, CuraScript SD Specialty Distribution, and Metro Medical (collectively, "the distributors") first purchased Eylea wholesale from Regeneron, and then sold it to medical practices. As part of its agreements with the distributors, Regeneron paid a distribution service fee to the distributors for services that included account set-up, shipping, and product storage for each unit of Eylea sold. Regeneron also reimbursed the distributors for the actual credit card processing fees charged by third-party financial institutions, on the

understanding that the distributors lowered the effective price of Eylea for doctors and medical practices using credit cards.

**E. Competition**

When Eylea came to market in 2011, it competed with two drugs manufactured by Genentech: Avastin and Lucentis. Eylea surpassed Lucentis's market share by the end of 2014, but it initially struggled to compete with Avastin -- a substantially more affordable treatment for Wet AMD. Indeed, Avastin remained the most popular Wet AMD treatment for at least Eylea's first five years on the market.

Regeneron knew that some medical practices considered a drug's potential profit when choosing which of the three to purchase for their practice. Medical practices often hired practice administrators whose responsibilities included tracking the spread, or profit, of different treatment options. Regeneron hired some of these same practice administrators to consult for Regeneron or speak at Regeneron events. Regeneron also tracked the profit of each drug -- Eylea, Lucentis, and Avastin -- itself.

When calculating the profit of a drug, medical practices considered credit card cashback rewards. Because of Eylea's high cost, the amount of cashback from the purchases of Eylea was significant, and the total profits often comprised a large portion of a medical practice's revenue. For example, one practice's cashback from Eylea purchases in 2019 approached $450,000. A

practice administrator told Regeneron that practices considered credit card rewards when determining the profit generated by a given drug.

While medical practices factored in credit card rewards when making purchases, Regeneron knew they were sensitive to the higher prices associated with using credit cards to purchase Wet AMD therapeutics. Typically, if medical practices used credit cards to purchase Lucentis or Avastin from the distributors, they incurred a processing fee to offset the fee charged by financial institutions to process credit card transactions. Customers paying with cash did not incur such a fee; as one distributor described in its standard invoice form, those customers received a "cash discount" that "[p]ayments by credit card [did] not receive." Dkt. 58 ¶ 76. In 2011, the year Eylea entered the market, Regeneron's Reimbursement Business Manager sent a company email describing how the processing fee for credit card payments was a "big deal" for medical practices. Id. ¶ 77. Accordingly, as early as 2011, Regeneron decided to reimburse the distributors for credit card processing fees for practices purchasing Eylea with credit cards.

Under Regeneron's credit card fee reimbursement arrangement, the distributors charged medical practices the same price for Eylea regardless of payment method. The distributors itemized the purchases with the waived credit card fees and sent an invoice to Regeneron. Regeneron would then pay the distributors the credit

card fees that the distributors would have received from the medical practices in addition to the standard distribution fee Regeneron paid distributors for the services rendered. In other words, had Regeneron not reimbursed the credit card fees, distributors would have charged medical practices more for buying Eylea with credit cards. From January 2018 through May 2021, Regeneron paid the distributors over $250 million for credit card processing fees for Eylea.

Meanwhile, when medical practices purchased Lucentis and Avastin from the distributors, they incurred a credit card processing fee of around 2.4%. However, physician customers of Lucentis had the option of purchasing Lucentis with a credit card directly from Genentech, the manufacturer, without a fee.

Regeneron marketed the lack of fees for using credit cards when purchasing Eylea from distributors and distinguished Eylea from its competitors on this basis. In addition, Regeneron acted swiftly to remedy instances where distributors erroneously charged customers for paying by credit card. In one instance, when a customer complained to Regeneron's Chief Executive Officer that he was not getting "a discount" and his credit cards were "cod[ed]" wrong, Regeneron executives reached out to the distributor's executives about the situation and followed up weeks later. Id. ¶ 88. In another example, when a distributor added a charge to the "cash only" price for a credit card customer, a Regeneron executive

asked the distributor to "correct" the issue "asap" because Regeneron "cover[s] [the] credit card pass thru costs." Id. ¶ 79.

**F. Bona Fide Service Fees**

Manufacturers of "buy and bill" drugs, especially when competing products enter the market, often face conflicting incentives. On the one hand, to maximize customer profit, manufacturers seek to maintain a high and stable ASP. Because Medicare and other payors reimbursed medical practices based on Eylea's reported ASP, the higher the ASP remained, the more profit the medical practices stood to gain. Furthermore, medical practices often tracked the ASP of different drugs, which were updated every quarter. The medical practices were sensitive to ASP fluctuations and sought stable financial options.

Meanwhile, to appeal to certain customers, manufacturers may seek to provide those customers with price concessions. However, doing so creates a lower ASP because manufacturers are obligated to deduct the price concessions given to purchasers from the reported ASP, which in turn lowers the potential profit for the entire physician market. During a 2013 presentation, Besse's parent company warned Regeneron of this phenomenon; in particular, the presentation explained that if Regeneron paid certain types of service fees, it would "likely result in lower reimbursement for the entire physician market." Dkt. 58 ¶ 114 (emphasis omitted). Regeneron knew this happened to Genentech -- Lucentis's ASP

declined after Genentech offered its customers rebates. Regeneron also knew that if it offered and reported discounts, it risked starting a "price war" with Genentech, "lead[ing] to a downward pricing spiral." Id. ¶ 121.

Regeneron hoped to increase its customers' cost recovery while keeping Eylea's ASP stable. Regeneron knew that paying for bona fide service fees ("BFSFs") was one method of decreasing the cost of Eylea without offering a reportable discount. As discussed more fully below, pursuant to 42 C.F.R. § 414.804(a)(2)(ii), a BFSF is not deducted from the ASP. In an internal document from 2016, Regeneron assumed the credit card fees qualified as a BFSF when calculating Eylea's ASP. The "[a]pprover" of this assumption, Alicia Pantaleo, emailed an employee from Deloitte, a consulting firm, two years later inquiring whether "we ever d[id] anything on credit card fees to substantiate that they were BFSF[s]." Id. ¶ 111. The following year, Deloitte reported to Regeneron that credit card fee reimbursements would not qualify as BFSFs.

Nonetheless, Regeneron continued to reimburse credit card fees without accounting for them in the ASP. As a result, Eylea's ASP remained stable. Regeneron marketed the stability and created graphics depicting Lucentis's declining ASP juxtaposed with Eylea's constant ASP. Absent Regeneron's payments, the distributors would have charged customers a higher price for using

credit cards, for example $44.40 more per vial of Eylea on a per unit cost of $1,850.

## II. Procedural Background

Relators filed this action against Regeneron in July 2020 and amended their complaint two years later. In 2023, the United States elected to intervene in part pursuant to 31 U.S.C. § 3730(b)(4). The United States filed its complaint on March 28, 2024, bringing FCA claims under 31 U.S.C. § 3729(a)(1)(A) and (B) and a claim for unjust enrichment under federal common law. Colorado, Georgia, Michigan, North Carolina, Texas, and Washington also partially intervened and filed a complaint bringing claims under their state-law analogs. Regeneron now moves to dismiss the federal- and state-law claims.

## LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, a complaint must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555 (cleaned up). This standard requires a court to "separate the complaint's factual allegations

(which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Kando v. R.I. State Bd. of Elections, 880 F.3d 53, 58 (1st Cir. 2018) (quoting Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012)). The court must then determine whether the factual allegations permit it "to draw the reasonable inference that the defendant is liable for the misconduct alleged." Germanowski v. Harris, 854 F.3d 68, 72 (1st Cir. 2017) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

## DISCUSSION

### I. Federal FCA Standard

The complaint relies on two provisions of the FCA that target distinct types of false claims. First, relying on the presentment theory, the complaint alleges that Regeneron "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Under this theory, fraud "has two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." Hagerty ex rel. United States v. Cyberonics, Inc., 844 F.3d 26, 31 (1st Cir. 2016).

Second, under a false statements theory, the complaint alleges that Regeneron "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false

or fraudulent claim" to the federal government. 31 U.S.C. § 3729(a)(1)(B).

As the First Circuit has explained, "[e]vidence of an actual false claim is 'the sine qua non of [an FCA] violation.'" Guilfoile v. Shields, 913 F.3d 178, 188 (1st Cir. 2019) (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004)). The plaintiff must also show that the defendant either "present[ed]" or "cause[d] to be presented" the false claim, 31 U.S.C. § 3729(a)(1)(A), or made or used a false statement "material to a false or fraudulent claim," id. § 3729(a)(1)(B). Under both provisions, the falsity must be material to the government's decision to pay. See Guilfoile, 913 F.3d at 187 & n.7.

Next, "[t]he FCA includes a scienter requirement that the false claim be submitted 'knowingly.'" Id. (quoting 31 U.S.C. § 3729(a)(1)(A), (b)(1)). The FCA defines "knowingly" to mean that the defendant "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "[P]roof of specific intent to defraud," however, is not required. Id. § 3729(b)(1)(B).

## II. Whether Credit Card Fee Reimbursements Qualify as "Price Concessions"

Regeneron's first argument for dismissal is that reimbursing distributors for credit card fees does not qualify as a price concession that must be deducted from Eylea's ASP. In Regeneron's view, its practice is no different from that of the ordinary business practice of charging customers "a single cash-or-credit price and thus allow[ing] some customers to buy products with a credit card (and potentially obtain rewards or cash-back) without paying an upcharge." Dkt. 146 at 10.[2] If Regeneron is correct, then the ASP reported for Eylea was not false or fraudulent under the FCA.

The key question is whether, under 42 U.S.C. § 1395w-3a(c)(3) and 42 C.F.R. § 414.804(a)(2), reimbursing distributors for credit card fees constitutes a "price concession." Regeneron urges the Court to interpret the statute and regulation as limiting price concessions to only the enumerated transactions. It argues that a manufacturer need not include in its ASP calculation an alleged price concession that is not explicitly mentioned in the statute and that the Secretary has not identified "other price concessions" beyond those enumerated in the statute. See 42 U.S.C. § 1395w-3a(c)(3).

But the plain language of the statute authorizes the Secretary to include "other price concessions" beyond those explicitly

[2] The government does not argue that the credit card cash rewards Eylea customers received were price concessions.

listed. Id. Under this authority, CMS promulgated the regulation, which states that "[p]rice concessions include the following types of transactions." 42 C.F.R. § 414.804(a)(2)(i) (emphasis added). As the Supreme Court has noted, "the term 'includ[e]' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle." Fed. Land Bank of St. Paul v. Bismarck Lumber Co., 314 U.S. 95, 100 (1941); see also Samantar v. Yousuf, 560 U.S. 305, 317 n.10 (2010) ("[T]he word 'includes' is usually a term of enlargement, and not of limitation[.]" (alteration in original) (quoting Singer & J. Singer, Sutherland on Statutory Construction 305 (7th ed. 2007))). By using "include," CMS created an illustrative list of price concessions. Moreover, other CMS guidelines frame the enumerated price concessions as examples, noting that manufacturers must "take into account price concessions such as" those enumerated. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48,982, 49,000 (Aug. 22, 2006) (emphasis added); accord Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B, 71 Fed. Reg. 69,624, 69,666 (Dec. 1, 2006).

Although interpreting "include" to be a "term of enlargement, and not of limitation," is the norm, as Regeneron points out, it

is not without exception. See Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Text 132-33 (2012) ("Even though the word including itself means that the list is merely exemplary and not exhaustive, the courts have not invariably so held." (quoting Garner's Dictionary of Legal Usage 439-40 (3d ed. 2011))). Oftentimes when a court interprets "include" as introducing an exhaustive list, the verb is followed by distinct categories that lack a unifying general principle. See, e.g., Carcieri v. Salazar, 555 U.S. 379, 391-92 (2009) (holding that Congress's use of "shall include" to define "Indian" created an exhaustive list because the phrase was followed by "only three discrete definitions"); Dong v. Smithsonian Inst., 125 F.3d 877, 880 (D.C. Cir. 1997) (finding a list following "includes" to be exhaustive when it lacked a "unifying" "general principle" and detailed distinct categories). The price concessions listed in the regulation have a unifying general principle: each listed transaction effectively reduces the cost for customers purchasing a drug. Therefore, the Court interprets the word "include" in the regulation as a term of enlargement rather than limitation.

Regeneron argues that unlike the enumerated price concessions, credit card fee reimbursements to distributors do not offer the credit card users (i.e., the medical practices) a discount or rebate; rather, in its view, distributors charge a single price for Eylea for credit card and cash users alike.

Regeneron offers examples from other markets (like pizza parlors) and commonplace transactions where consumers are routinely charged the same price for an item or service regardless of payment method.

To support its argument, Regeneron relies on United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39 (D. Mass. 2011). In Westmoreland, the district court held that "overfill," the practice of placing excess drugs in a vial to help with withdrawal and administration of the labeled amount, was not a price concession. Id. at 67. Key to that ruling was the fact that excluding overfill as a price concession was "a conscious choice" by CMS, which promulgated a 2010 final rule that explicitly discussed and dismissed overfill as a price concession while simultaneously prohibiting medical practices from submitting reimbursement requests for any overfill used. Id. at 65. In contrast, CMS has not made a similar decision regarding credit card processing fee reimbursement.

The government argues that reimbursing credit card fees so that credit card users pay a lower price effectively gives them a price concession. This is a plausible claim. As the complaint alleges, Regeneron's customers themselves understood the reimbursements as "discount[s]" and so did Regeneron executives. In addition, competitor Genentech did not reimburse credit card fees for Aventis and Lucentis, so medical practices paid higher prices when they used credit cards to purchase those drugs from

distributors. Accordingly, while the statute and regulation do not expressly identify credit card fee reimbursements as a deductible price concession, the regulation broadly requires manufacturers to deduct all price concessions, and the complaint plausibly alleges that this included the credit card fee reimbursements in light of prevailing industry practices.

## III. Whether the Credit Card Fee Reimbursements Constitute Bona Fide Service Fees ("BFSFs")

The second question is whether the credit card fee reimbursements were BFSFs that did not need to be deducted from Eylea's ASP. Regeneron contends that credit card processing fees should be treated the same as shipping fees, which distributors likewise incur as part of distribution and manufactures likewise reimburse.

CMS's regulation exempts BFSFs from the definition of "price concessions." See 42 C.F.R. § 414.804(a)(2)(ii). Again, to qualify as a BFSF, the fee must:

> represent [1] fair market value [2] for a bona fide, itemized service actually performed on behalf of the manufacturer [3] that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and [4] that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Id. § 414.802 (numbering added). Failure to meet any one prong disqualifies a fee as a BFSF. Regeneron posits that all four prongs

are satisfied. The government argues that Regeneron's credit card fee reimbursements fail the second, third, and fourth criteria.

Because the Court concludes that the fee does not qualify under the second prong, the Court does not address prongs three and four. Under the second prong, the government argues that the credit card fee reimbursements do not represent payment for a distribution service performed on Regeneron's behalf. In response, Regeneron asserts that the fee is for the service of credit card processing and is no different than paying for any other distribution service such as shipping costs, which Regeneron typically pays for. The government concedes that shipping costs are BFSFs. In both instances, Regeneron pays the distributor for acts done by third parties -- in the case of credit card processing, financial institutions, and in the case of shipping, transporters. Regeneron argues that reimbursing shipping services benefits medical practices who theoretically could be charged for shipping.

The CMS guidance to the BFSF rule clarifies that CMS "interpret[s] these [BFSF] elements . . . to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other

Changes to Payment Under Part B, 71 Fed. Reg. at 69,668. As the government persuasively points out, credit card services, unlike shipping services that deliver the drugs, are not necessary or useful for the "efficient distribution" of drugs. Moreover, credit card fees are paid "on behalf of" customers, not on behalf of the manufacturers, to reduce their cost and improve their profit. Accordingly, the government has persuasively argued that these reimbursements do not qualify as a "bona fide, itemized service actually performed on behalf of the manufacturer." 42 C.F.R. § 414.802.

## IV. Scienter

Regeneron argues that the complaint fails to adequately plead scienter. Under the FCA's scienter requirement, "knowingly" includes three mental states:

> First, that the person "has actual knowledge of the information." Second, that the person "acts in deliberate ignorance of the truth or falsity of the information." And, third, that the person "acts in reckless disregard of the truth or falsity of the information." In short, either actual knowledge, deliberate ignorance, or recklessness will suffice.

United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 749–50 (2023) (citations omitted) (quoting 31 U.S.C. § 3729). The FCA does not require proof of specific intent to defraud; liability arises as long as one of these three mental states is established. See id. at 750 n.3. The Supreme Court has clarified that scienter under the FCA is assessed subjectively, focusing on the defendant's

actual knowledge and beliefs rather than those of a hypothetical reasonable person. See id. at 749. Under this subjective standard, "even though [a regulatory phrase] may be ambiguous on its face, such facial ambiguity alone is not sufficient to preclude a finding that [defendant] knew [its] claims were false." Id.

The government plausibly alleges that Regeneron knowingly failed to include credit card processing fee reimbursements as price concessions. For example, the government claims Regeneron was aware that some medical practices selected Wet AMD drugs based on their profitability. When calculating potential profit, medical practices factored in credit card rewards, reimbursement rates, and ASP stability. By reimbursing credit card processing fees without including the reimbursements in its ASP calculations, Regeneron enhanced all three factors: Eylea's ASP stayed stable, unaffected by the credit card processing fee reimbursements; the profit spread increased, as credit card customers paid less for Eylea while Medicare reimbursements remained constant; and medical practices were able to reap the benefits of credit card rewards without paying extra fees. The complaint also claims that customers understood the reimbursement to constitute a "discount" and referred to them as such in at least one call to a Regeneron executive. Dkt. 58 ¶ 88. The complaint further alleges that Regeneron ignored a Deloitte report indicating that the reimbursements did not qualify as BFSFs.

Regeneron presents an alternative argument: it should not be held liable even if it was obligated to report the reimbursements because its calculation of Eylea's ASP was, at the very least, reasonable. Regeneron's argument hinges on CMS guidance instructing manufacturers to "make reasonable assumptions in [their] calculations of ASP," "[i]n the absence of specific guidance." Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. at 49,004. CMS instructs manufacturers to "include [the] assumptions in their ASP submissions." Id.[3] Regeneron contends that it reasonably assumed credit card fee reimbursements did not constitute price concessions in the absence of adequate guidance on ASP calculation.[4] Accordingly, Regeneron frames the question as

[3] A spreadsheet titled "Regeneron Pharmaceuticals -- Reasonable Assumptions for April 2016 Monthly Average Manufacturer Price (AMP)" is attached to the government's complaint. Dkt. 58-43. Each page of the document includes the disclaimer: "[t]his document is intended solely for the information and internal use of Regeneron Pharmaceuticals and should not be used or relied upon by any other person or entity." Id. At the motion to dismiss stage, it is unclear whether the document was ever submitted to CMS.

[4] Regeneron supports its claim that CMS failed to provide sufficient guidance by selectively quoting from a 2022 Department of Health and Human Services Office of Inspector General ("OIG") report, which called on CMS to provide more guidance for calculating ASP and identified nine areas requiring clarification. However, notably absent from the OIG's recommendations were issues related to the definition of price concessions in general and credit card processing fees in particular. OIG's recommendations concerning BFSFs were limited to two criteria not relied on here,

"whether 'reasonable minds may differ' with [the government's] view that credit card processing fees must be included in ASP." Dkt. 146 at 42 (quoting United States ex rel. Jones v. Brigham & Women's Hosp., 678 F.3d 72, 87 (1st Cir. 2012)).

Even if the definition of a BFSF is ambiguous, and even if Regeneron's current interpretation is reasonable, the argument is unpersuasive. The Supreme Court in SuperValu made clear that the relevant inquiry under the FCA is Regeneron's subjective state of mind at the time of the alleged misconduct. See SuperValu Inc., 598 U.S. at 749. Drawing all reasonable inferences in the government's favor, the Court concludes that it is plausible that Regeneron knowingly failed to deduct the credit card fee reimbursements from Eylea's ASP in order to gain a competitive advantage.

## V. False Claim

Regeneron next contends that the complaint fails to allege falsity in any claim for payment presented to the government. For a false statement to be actionable under either 31 U.S.C. § 3729(a)(1)(A) or § 3729(a)(1)(B), it must be made in connection

clarifying "fair market value" and "what constitutes sufficient evidence of knowledge that a fee is passed through." U.S. Dep't of Health and Hum. Servs. OIG, OEI-BL-21-00330, Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices 13 (2022), https://oig.hhs.gov/documents/evaluation/3215/OEI-BL-21-00330-Complete%20Report.pdf.

with a false or fraudulent claim. The government argues that this requirement has been met for two reasons. First, by reporting a falsely inflated ASP, Regeneron caused Medicare to pay for Eylea claims at an inflated rate. According to the government, Regeneron submitted these false ASP reports knowing Eylea customers would rely on the reported ASP to submit claims for reimbursement to Medicare. Second, medical practices certified that their claims for Eylea complied with Medicare regulations, which was false because of Regeneron's misconduct.

This Court has long held that a claim predicated on an underlying fraudulent pricing scheme is false although the claim itself may not contain a fraudulent price. See In re Pharm. Indus. Average Wholesale Price Litig. ("AWP"), 478 F. Supp. 2d 164, 172-73 (D. Mass. 2007). Regeneron argues that the AWP line of cases is not controlling because the FCA was amended in 2009. According to Regeneron, since 2009, the FCA has clarified that there must be a falsehood in an actual "request or demand . . . for money or property." 31 U.S.C. § 3729(b)(2)(A). In its view, the claims submitted by the medical practices to CMS did not make false statements, and the false statements made by Regeneron about ASPs were not claims for money or property. Regeneron further argues that the claims submitted by Eylea's customers were not false because they did not specifically certify compliance with ASP reporting.

The basis of Regeneron's first argument is flawed. The definition of "claim" is "any request or demand, whether under a contract or otherwise, for money or property . . . that . . . is presented to an officer, employee, or agent of the United States." Id. The 2009 amendment merely relocated this definition from § 3729(c) to § 3729(b)(2)(A); it did not alter the language or impose a heightened requirement that the falsehood itself be embedded in the request for payment. Rather, the government's theory falls within the scope of the FCA: that Regeneron violated the statute by submitting false ASP reports that caused, and were material to, the submission of false claims for payment for Eylea at falsely inflated prices.

Nor do the cases cited by Regeneron support its argument that, post-2009, FCA liability attaches only when the falsehood appears on the face of the submitted claim. In United States ex rel. Booker v. Pfizer, Inc., the First Circuit held that, as is alleged here, "FCA liability attaches" when "fraudulent conduct affecting the government . . . resulted in the filing of a false claim for payment from the government." 847 F.3d 52, 57 (1st Cir. 2017) (cleaned up), aff'g 9 F. Supp. 3d 34 (D. Mass. 2014). The other cases cited by Regeneron involved dismissal under Rule 9(b) where the complaints failed to identify specific claims submitted to the government, an issue not present here since the government has provided a table of claims to Medicare for Eylea reimbursement,

including specific dates and amounts. See United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 124 (1st Cir. 2013) (affirming dismissal under Rule 9(b) when relator provided "at most, aggregate expenditure data . . . with no effort to identify specific entities who submitted claims or government program payers"); United States ex rel. Grant v. United Airlines Inc., 912 F.3d 190, 197 (4th Cir. 2018) (affirming dismissal under Rule 9(b) when relator failed to allege that fraudulent "scheme necessarily led to the presentment of a false claim to the government for payment").

Moreover, as the Supreme Court explained in Universal Health Services, Inc. v. United States ex rel. Escobar ("Escobar"), false claims can also arise under an "implied false certification" theory, where a claimant's failure to disclose noncompliance with material statutory or regulatory requirements renders its representations misleading half-truths. 579 U.S. 176, 186, 190 (2016). This is true even if the entity submitting claims does not know about the non-submitting entity's unlawful conduct. See United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 390 (1st Cir. 2011).[5] Here, the government argues that each time a medical practice submitted a claim for reimbursement, it

[5] Regeneron urges the Court to read the First Circuit's recent opinion in Humana Inc. v. Biogen, Inc., 126 F.4th 94 (1st Cir. 2025), as narrowing Escobar. See Dkt. 169. However, Humana was concerned with whether the plaintiff met the pleading standards for a RICO claim premised on mail and wire fraud under Rule 9(b). Id. at 103-04.

certified compliance with "all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment." Dkt. 151 at 36. This statement was false given Regeneron's inaccurate ASP reporting.

Because the complaint plausibly alleges that Regeneron knowingly inflated Eylea's ASP, resulting in false claims to the government and implied false certifications of compliance with Medicare requirements, and identifies specific claims submitted by Eylea customers to the government, the allegations sufficiently establish falsity under the FCA.

## VI. State Law Claims

Finally, Regeneron asserts that the plaintiff-States' claims under various state analogs of the federal FCA fail for the same reasons as its federal claims. The plaintiff-States respond that even if dismissal is warranted on the federal claims, the claims under Texas law survive. Since this Court denies the motion to dismiss as to the federal claims, the Court denies the motion with respect to the state claims as well and need not visit purported differences between the FCA and the Texas analog at this juncture.[6]

[6] Regeneron also moves to dismiss the claims of unjust enrichment. However, unjust enrichment may be pled against Regeneron as an alternative theory of liability. See Fed. R. Civ. P. 8(d)(3).

**ORDER**

For the reasons stated above, Regeneron's motion to dismiss (Dkt. 145) is **DENIED**.

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge